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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,316	09/30/2003	Alvin Algee	A03P1065	6514

36802 7590 02/25/2005

PACESETTER, INC.  
15900 VALLEY VIEW COURT  
SYLMAR, CA 91392-9221

EXAMINER
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GREENE, DANA D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/676,316

Applicant(s)

ALGEE, ALVIN

Examiner

Dana D. Greene

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-30-03</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 – 15, drawn to the apparatus, classified in class 607, subclass 116.
  - II. Claims 16-21, drawn to a method of fabricating, classified in class 128 and subclass 898.

If two or more independent and distinct inventions are claimed in one application, the Examiner in an Office Action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (see 37 C.F.R. §1.142).

In addition to the different classifications of Groups I and II, the method of fabricating the implantable medical lead can be used for more than just providing stimulation to selected body tissue. For example, the method of implantable medical lead fabrication is common in administering specific types of medical treatment and effecting medical procedures (see col. 1, ln. 15-20 of US 5,766,234).

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Applicant's election without traverse of claims 1-15 in the phone conversation with Mr. Derrick Reed on 2-18-05 is acknowledged.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Helland (US 5,628,774, hereinafter “Helland”). Helland is considered to disclose:

an implantable medical lead comprising a lead body having a proximal end carrying a connector assembly adapted to be received by an implantable medical device and a distal end, and at least one electrode connected to the lead body (see col. 3, ln. 65 – col. 4, ln. 10, Helland). The disclosed lead body is considered to anticipate the claimed lead body because both share the same shape and configuration.

an insulating housing defining an outer surface and enclosing at least one electrical conductor connecting the at least one electrode with the connector assembly (see col. 4, ln. 10-20, Helland). The disclosed outer insulation is considered to anticipate the claimed insulating housing because both surround the conductor and form an insulation that extends from the electrode to the connector.

a flexible membrane surrounding said insulting housing having an inner surface confronting the outer surface of the housing (see col. 4, ln. 18-20, Helland). The disclosed second insulation is considered to anticipate the flexible membrane because both contact the insulating housing or the first insulation.

a lubricious medium disposed between the inner surface of the membrane and the outer surface of the housing (see col. 5, ln. 33-52, Helland). The disclosed polyurethane material is considered to anticipate the lubricious medium material because both materials facilitate movement in response to frictional engagement.

With regards to claims 2-3, Helland discloses a sealed space (see col. 7, ln. 5-15, Helland). The disclosed insulation is considered to anticipate the seal around the space between the confronting surfaces.

Referring to claims 7-10, Helland discloses a membrane with a tubular configuration disposed on the outer surface (see col. 5, ln. 58-60, Helland).

With reference to claim 11, Helland teaches a housing fabricated of silicone rubber (see col. 5, ln. 45-50, Helland).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

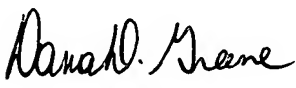
Claims 4-6 and 12-15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Helland in view of Carson (US 6,078,839, hereinafter "Carson"). Helland is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed lubricious medium composition of a biocompatible material. However, Carson is considered to disclose the claimed medical grade material (see col. 2, ln. 50-55, Carson). It would have been obvious to one of ordinary skill in the art to combine the teachings of Helland with the considered medical grade material teaching found in Carson for the function of the lubricious medium.


***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Dana D. Greene

  
George Manuel  
Primary Examiner

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